Attorney Docket No.: 66631.8001.US01

#### REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office Action dated August 9, 2010 are respectfully requested. A separate petition for a three-month extension of time accompanies this amendment.

#### I. Interview Summary

Applicants thank Examiners Holt and Richter for granting Applicants a telephonic interview on February 8, 2011. Compliant with M.P.E.P. § 713.04, Applicants hereby provide the following summary of the interview. The cited prior art document of Penners et al. (CA 2,143,500), forming the basis of the rejection under 35 U.S.C. § 103 in the October 9, 2010 Office action, was discussed. Also discussed was the double patenting rejection presented by Examiner Holt in the October 9, 2010 Office action. During the telephonic interview, agreement was reached that incorporation of the features of claim 31, specifically, the time period of 4 to 9 hours, into independent claim 1, would place the application in condition for allowance.

## II. Amendments to the Claims

Claim 1 is amended to incorporate the features of claim 31. Claim 22 is amended to change the dependency to claim 1. Claim 29, which is currently withdrawn, is amended to change the dependency to claim 1.

Claims 30 and 31 are canceled with this amendment.

No new matter is introduced by way of this amendment.

## II. Double-Patenting Rejection

Claims 1, 8-14, and 30-31 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 19-20 and 40 of U.S. Patent No. 6,340,475.

Claim 1 is amended to incorporate the features of claim 31, specifically reciting a time period of 4 to 9 hours. As discussed in the Interview Summary above, Examiners Holt

and Richter agreed that this amendment would place the present claims in condition for allowance. Claims 30 and 31 are cancelled with this amendment.

Applicants respectfully request withdrawal of the obviousness-type double-patenting rejection.

## II. Rejections under 35 U.S.C. § 103

Claims 1, 5, 8-14, 18-20, 22-28, and 30-31 were rejected under 35 U.S.C. § 103 as allegedly obvious over Penners et al. (CA 2,143,500; herein "Penners") in view of Ciprofloxacin Patient Information Sheet and the Cipro® Drug Information Sheet (2000) (herein "Cipro drug information sheet").

As discussed above in the Interview Summary, Examiners Holt and Richter stated that incorporation of the time period of 4-9 hours as recited in claim 31, into independent claim 1, would overcome the rejection under 35 U.S.C. § 103 and place the claims in condition for allowance.

Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103.

## III. Request for Withdrawal of the Final Rejection

In view of the agreement regarding amendment to the pending claims to place them in condition for allowance, Applicant recognizes that the remarks in this section should be moot. However, and merely as a precautionary matter to preserve Applicants' rights, Applicants formally request withdrawal of the finality of the rejection in the August 9, 2010 Final Office action (hereafter "Final Office action"). According to M.P.E.P. § 706.7(a), under present practice, second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).

Applicants note that claims 1, 8-14 and 30-31 stand rejected on the ground of nonstatutory obviousness-type double patenting in view of U.S. Patent No. 6,340,475 ("the '475 patent"). However, in the previous Office Action (dated January 20, 2010), the

Examiner stated that claims 4-5 and 8-10 would be allowable if rewritten in independent form including all limitations of the base claim and any intervening claims. In response, Applicant incorporated the features of claim 4 into claim 1.

The Examiner then issued the Final Office action, wherein for the first time claims 8-10 were rejected for nonstatutory obviousness-type double patenting in view the '475 patent. Applicants submit that the new rejection of claims 8-10 in a Final Office action is improper, for at least these reasons.

First, the rejection of the claims 8-10 in the obviousness-type double-patenting rejection in the Final Office action constitutes a new ground of rejection that was not necessitated by Applicants' amendment of the claims, since the amendment to claim 1 merely incorporated the feature of dependent claim 4, which like claims 8-10 was not subject to the double-patenting rejection made in the prior rejection. There is no rational basis for asserting that including a feature of a dependent claim not subject to the double-patenting rejection into the independent claim renders another, unrelated dependent claim newly subject to a double-patenting rejection. Second, rejection of claims 8-10 for obviousness-type double patenting in the current final Office action is not based on information submitted in an information disclosure statement as evidenced by the fact that the Examiner does not rely on any art other than the '475 in the double-patenting rejection.

As the '475 patent was previously cited in the double patenting rejection presented by the Examiner in the Office action dated 4/22/2010, and the Examiner could have and should have rejected claims 8-10 at that time, it is unfair to newly reject claims 8-10 in the Final Office action. Accordingly, Applicants submit that rejection of claims 8-10 on the ground of non-statutory obviousness-type double patenting is a new ground of rejection neither necessitated by Applicant's amendment of the claims, nor based on information submitted in an IDS, and Applicants respectfully request that the Examiner reconsider and withdraw finality of the Office action mailed October 9, 2010.

# VII. Conclusion

For the reasons above, Applicants respectfully submit that the pending claims are in full condition for allowance. A Notice of Allowance is therefore respectfully requested.

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If the Examiner has any questions or believes a telephone conference would expedite the prosecution of this application, Applicants request that the Examiner call the undersigned at (650) 590-1919.

No fees, beyond the fee for three-months extension of time and the Notice of Appeal, are believed due with this communication. However, the Commissioner is hereby authorized and requested to charge any deficiency in fees herein to Deposit Account No.: 50-4616.

Respectfully submitted,

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